IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	David E. Francischelli et al.	Examiner: Peter J. Vrettakos
Serial No.:	10/792,178	Group Art Unit: 3739
Filed:	March 3, 2004	Docket No.: M190.253.101/P-8575.06
Due Date:	July 9, 2008	
Title:	VIBRATION SENSITIVE ABLATION DEVICE AND METHOD	

RESPONSE TO NON-COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Response to Non-Compliant Appeal Brief is submitted in response to the Notification of Non-Compliant Appeal Brief mailed July 25, 2008.

This Appeal Brief is submitted in support of the Notice of Appeal filed on May 9, 2008, appealing the final rejection of claims 25-33 of the above-identified application as set forth in the Final Office Action mailed January 9, 2008.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of $510.00 for filing a Brief in Support of an Appeal as set forth under 37 C.F.R. § 41.20(b)(2). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 25-33.

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences know to the Appellant that will have a bearing on the Board's decision in the present Appeal.

STATUS OF CLAIMS

The application as originally filed contained claims 1-79. Claims 1-24 and 34-61 were withdrawn from further consideration as a result of an Office Action mailed on February 27, 2006, as being directed to a non-elected invention. The Office Action also examined claims 25-33, which were elected for prosecution.

In the Office Action mailed on January 9, 2008, claims 25-33 were pending and rejected. This Office Action was not a final rejection, but Appellant chose to appeal the at least twice-rejected claims in the Notice of Appeal mailed on May 9, 2008.

Claims 25-33 remain pending and are the subject of this Appeal. Claim 25 is the only independent claim, and claims 26-33 depend either directly or indirectly from claim 25.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the last Office Action on the merits mailed January 9, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

This Summary sets forth specific examples and solutions that might be realized with the claimed subject matter. The reference numerals and descriptions are intended for the ease of understanding the claimed subject matter in this appeal. Appellant does not mean to limit the claims to the described examples or otherwise with this Summary.

A. Introduction to the Problem Facing the Appellant

The claims on appeal relate to various examples of ablation devices, such as ablation devices to provide energy for therapeutic ablation of organic tissue such the human heart.

Ablation devices are used for several purposes, including forming lesions in the heart for the treatment of atrial fibrillation. Atrial fibrillation can be treated with ablation of cardiac conduction pathways in the region of tissue where malfunctioning heart signals occur. The ablation devices in the examples are capable of monitoring the level of energy being used to ablate the tissue and of preventing the energy from creating tissue-damaging events such as a "steam pop."

Water in and near the ablation site when heated can cause ruptures in healthy tissue, which can result in undesired effects on the tissue and the patient. If the temperature of the water in and near the ablation site reaches and then exceeds its boiling point, the water will change phase, boil, and may result in an audible steam pop within the tissue. Irrigation cooling of the site shifts the location of the steam pop even deeper within the tissue, which results in even greater damage than a superficial pop.

Temperature sensors and other detectors in the tissue are not always reliable indicators of a damaging steam pop. For example, the temperature within irrigated tissue may be much higher than the ablation electrode, and thus the temperature of the tissue subject to a steam pop does not necessarily correspond with the temperature measured at the ablation electrode. Further, the mere existence of steam or a temperature at the boiling point may indicate at times a predisposition of a steam pop, but it does not necessarily warrant an immediate reduction in ablation energy. Often, steam pops do not occur in such situations if the steam is able to escape or if the water at boiling temperature is going through a phase change rather than actually boiling.

It has been observed, however, that mechanical vibrations occur in tissue prior to a steam pop. Although the true cause and effect is not known, scientists suspect the mechanical vibrations occur during the time period of the phase change as microbubbles within the tissue are formed. The mechanical vibrations are transferred to the ablation device.

The present claims provide for a method of ablating organic tissue where the mechanical vibrations are sensed, the surgeon is alerted, and/or the ablation is halted or reduced at the appropriate time.

B. The Claims

Independent claim 25 is directed to a method of ablating organic tissue. Claim 25 sets out "positioning an electrode adjacent the organic tissue," and "supplying electrical power to the electrode to effect ablation of the organic tissue." In example support of these features, the specification provide a surgeon or other user may manipulate an ablation apparatus 20 so that an electrode 22 contacts the surface of the tissue to be ablated (see page 6, lines 27-28 and Figure 1). A power source 30 provides electrical power to the apparatus 20 via a connection 28, and the power can be standard electrical power available in the operating room (see page 6, lines 28-32 and Figure 1).

Another feature of claim 25 includes "sensing with a sensor positioned adjacent the electrode the vibration of the organic tissue being ablated." In example support of these features, the sensor 24 may be permanently or removably incorporated into the ablation apparatus 20 near one of the electrodes 22, 23, and the sensor is used to sense mechanical vibration of the tissue that occurs prior to a "steam pop" (page 8, lines 28-29 to page 9, lines 3-4, and Figure 2).

Still another feature of claim 25 includes "the vibration is self generated in the organic tissue in response to the ablation." Support for this can be found at page 3, lines 29-31 where the steam pop is described. The damaging steam pop is preceded by a mechanical vibration in response to the heating of the tissue through the application of ablation energy. For example, the sensor is included to sense the actual mechanical vibration as it occurs directly, including through the tissue or through the ablation device (page 8line 18, to page 9, line 10.) The sensor senses the mechanical vibrations directly, rather than inferentially such as based on a reflected ultrasound signal broadcast into the tissue, for example. In other words, the sensor senses the mechanical vibration (or simmering vibrations as described at page 10, lines 21-30) preceding the steam pop rather than some reflected signal broadcast into the tissue that provides a measurement or representation of the mechanical vibration.

Claim 25 also includes "reducing power to the electrode when the vibration reaches a given value." Support for this feature is included at pages 10, lines 25-28 and page 11, lines 3-4 where simmering vibrations are sensed by the sensor 24 that provides a signal to an output device 25. The output device 25, for example, can be a switch or regulator that at the

signal from the sensor 24 adjusts power, turns on power and/or turns off power from source 30.

Claim 27 depends directly from claim 25, and further includes the features of "supplying fluid from a fluid supply to the tissue" and "halts[s] the fluid supply when the vibration reaches a given value." Support for this feature is included from page 10, line 30 to page 11, line 3 that states if the ablation is being irrigated from irrigation source 40, the switch or regulator may adjust the fluid flow, turn on fluid flow and/or turn off fluid flow from irrigation source 40 (see also figure 2).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 25-26 and 28-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nardella, U.S. Patent No. 5,733,281 ("Nardella I").

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella I in view of Nardella, U.S. Patent No. 5,334,193 ("Nardella II").

ARGUMENT

Claims 25-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nardella I. To anticipate a claim under 35 U.S.C. 102, a reference must teach every limitation of the claim.[1] Appellant respectfully submits that Nardella I does not teach every limitation of the each of the claims and requests removal of this ground of rejection.

The Office Action mailed on January 8, 2008, rejected the group of claims including independent claim 25 and its dependent claims 26 and 28-33 as being anticipated by Nardella I. Appellant submits independent claim 25 is patentably distinguishable from Nardella I, and dependent claims 26 and 28-33 are also patentably distinguishable from Nardella I, for at least the reasons set forth below. Claim 25 sets forth the requirements of "sensing with a sensor positioned adjacent the electrode the vibration of the organic tissue being ablated wherein the vibration is self generated in the organic tissue in response to the ablation" and "reducing power to the electrode when the vibration reaches a given value" (emphasis supplied). Appellant argues this feature is not taught or made obvious in Nardella I.

Nardella I teaches an electrosurgical feedback system for tools such as ablation catheters. The feedback system includes an acoustic feedback system that regulates the application of energy to the tissue. Nardella I figure 1 illustrates an acoustic and impedance feedback electrosurgical system 10 where an ultrasonic transducer 20 is mounted proximal to the energy-delivering electrode 12 (column 4, lines 20-30). An acoustic stage 50 is coupled to the transducer 20. The acoustic stage induces the "transducer 20 to resonate and thus produce ultrasonic waves. These waves are typically reflected by the tissue or other components in the vicinity of the tissue, e.g. steam or other gases, and are received by the

[1] Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). See also Atlas Power Co. v. IRECO Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1946 (Fed. Cir. 1999).

transducer 20, which produces corresponding electrical signals that are received and processed by the acoustic stage 50" (column 4, lines 49-54). The transducer-emitted waves are at "a diagnostic level of energy rather than at a therapeutic level of energy" (column 8, lines 31-32) and thus contribute nothing to the ablation. The ultrasonic transducer 20 and the associated processing circuitry" are used "specifically to determine and/or monitor the presence of steam at the surgical site" (column 8, lines 32-37). A clinician "specifically monitor[s] the effects of steam levels at the site. If the levels of steam are above a selected level or outside of a selected range, the analyzer circuit 130 can regulate the application of energy to the tissue" (column 8, lines 51-55).

Nardella I attempts to deal with the problem of steam pops but does so in a less effective and reliable way than the method set forth in claim 25. For example, Nardella looks for the presence of steam caused by the ablation. The detection of steam is often too late to prevent a steam pop. The limitations of claim 25, however, require "sensing . . . vibration of the organic tissue being ablated wherein the vibration is self generated" and "reducing power to the electrode when the vibration reaches a given value." The vibrations precede the formation of steam in the tissue. The detected steam of Nardella I is immediately before or concurrent with the steam pop, after the steam pop, or not at all related to a steam pop. The detection of vibrations as discussed above is prior to the steam even being formed.

The Office Action first argues that Nardella I "discloses an ablation method using vibration feedback," and the "source of the vibration includes that that is self generated (and not merely that emitted by Nardella's transducer)." The Office Action cites Nardella I at column 2, lines 48-55 for the teaching Nardella I "detects the effects of energy on tissue (self generated) such as the generation of steam created during energy application/heat generation." The ultrasonic vibrations taught in Nardella I are generated in the transducer, and the transducer senses the reflections of these ultrasonic vibrations. The transducer generated waves are indeed affected by the steam when they are reflected, but these reflections are still reflections of the transducer emitted-waves at a diagnostic energy level. Claim 25 is distinguishable from a method sensing reflections of transducer-emitted waves as it requires "sensing with a sensor . . . the vibration of the organic tissue being ablated wherein the vibration is self generated in the organic tissue."

In order to make this rejection, the Office Action relies on several interpretations or assumptions that are simply not true. For example, the Office Action equates steam or other gases from Nardella I with the claimed "vibration of the organic tissue being ablated wherein the vibration is self generated in the organic tissue." There is no indication or teaching in Nardella I or elsewhere that the "vibrations" in claim 25 has anything to do with the steam or other gases of Nardella I. Also, there is no teaching or recognition that steam vibrations rather than steam itself is detected by the reflected transducer-emitted waves.

Even if the transducer of Nardella detected a reflected wave off of steam vibration, the present claims do not require the detection of steam, and the claimed method would not work if steam was detected. By the time the transducer senses steam it may in fact be too late to prevent a steam pop. Instead, the claims sense self generated vibrations in the organic tissue being ablated in the requirement that "vibration of the organic tissue being ablated wherein the vibration is self generated in the organic tissue." The presence of these vibrations, prior to the presence of steam, are the most reliable known indicators of an impending steam pop, and that is why the present invention is directed at these vibrations rather than temperature or other indicators such as the presence of steam.

The Office Action also argues that "The waves generated by the ablation of [Nardella I] inherently affect the emitted waves from the transducer" in that the "[s]elf-generated vibrations due to ablation affect the emitted pulse during the reflection." Appellant does not dispute this point here. The Office Action incorrectly concludes, however, that "therefore the vibration feedback system is controlled by self generated as well as transducer emitted pulses." In support of this conclusion the Office Action states, "To say otherwise is to argue that the [Appellant's] ablation causes self-generated waves in the tissue, but [Nardella I's] does not."

The vibration feedback system taught in Nardella I is not controlled by self generated pulses as well as transducer generated pulses. The Office Action confuses detection with control. Even if self generated vibrations are detected in the system of Nardella I, they do not control the feedback system. The detection of steam levels, rather than the claimed vibrations, controls the feedback system of Nardella I. More particularly, the method in Nardella I has a clinician "specifically monitor[ing] the effects of steam levels at the site. If the levels of steam are above a selected level or outside of a selected range, the analyzer

circuit 130 can regulate the application of energy to the tissue." Accordingly, Nardella I does not teach the claimed feature of "reducing power to the electrode when the vibration reaches a given value."

In summary, Nardella I does not teach every limitation of claim 25. Nardella I detects reflected, transducer-emitted waves rather than the claimed features of "vibration of the organic tissue being ablated wherein the vibration is self generated in the organic tissue in response to the ablation." Also, Nardella I senses the presence of steam or other gases rather than the claimed feature of vibration that is "self generated in the organic tissue in response to the ablation." Further, to the extent that self generated vibrations reach the senor of Nardella I, Nardella disregards these vibrations in the feedback system. Nardella I monitors steam levels at the ablation site to regulate the application of energy to the tissue rather than the claimed feature of "reducing power to the electrode when the vibration reaches a given value." Appellant respectfully submits that Nardella I does not anticipate claim 25.

Further, there is nothing in Nardella to indicate the recognition of mechanical vibrations in the tissue preceding a steam pop. Nardella looks for the presence of steam, which is a less effective way of dealing with the problem facing applicants. In order to modify the system of Nardella I, the transducer-emitting waves would no longer be generated, and the processing circuitry substantially modified to no longer detect the presence of steam. Accordingly, Appellant submits that the teachings of Nardella I alone or in combination with any reference to make obvious the limitations of claim 25.

By virtue of their dependency to claim 25, claims 26 and 28-33 are also patentably distinguishable from Nardella I.

Claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella I in view of Nardella II. Claim 27 depends directly from claim 25 which has been shown to be patentably distinguishable from Nardella I. Nardella II teaches a fluid cooled ablation catheter, and it does not teach the features of claim 25 discussed above or even a vibration detection system. Because these features are missing from each of the references separately, they would be missing from any proposed combination of the references. Accordingly, Appellants submit that claim 27 is patentably distinguishable over the combination of Nardella I and Nardella II.

CONCLUSION

In view of the above, Appellant respectfully submits that pending claims 25-33 are in form for allowance and are not taught or made obvious by the prior art of record. Therefore, reversal of the rejections of claims 25-33 is respectfully requested.

Any inquiry regarding this Appeal Brief to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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CLAIMS APPENDIX

1-24 (Canceled)

25. (Previously Presented) A method of ablating organic tissue, comprising:

positioning an electrode adjacent the organic tissue;

supplying electrical power to the electrode to effect ablation of the organic tissue;

sensing with a sensor positioned adjacent the electrode the vibration of the organic tissue being ablated wherein the vibration is self-generated in the organic tissue in response to the ablation; and

reducing power to the electrode when the vibration reaches a given value.

26. (Original) The method of claim 25, further comprising:

halting the power when the vibration reaches a given value.

27. (Original) The method of claim 25, further comprising:

supplying fluid from a fluid supply to the tissue; and

halting the fluid supply when the vibration reaches a given value.

28. (Original) The method of claim 25 further comprising:

sending a signal from the sensor to a switch to reduce the power.

29. (Original) The method of claim 25, further comprising:

providing output from an output device when the vibration reaches a given value.

30. (Original) The method of claim 29 further comprising:

sending a signal from the sensor to the output device; and sending an indicator signal from the output device.

31. (Original) The method of claim 25 wherein the sensor is a piezoelectric crystal.

32. (Original) The method of claim 25 wherein the sensor is a piezoelectric polymer.

33. (Previously Presented) The method of claim 25 wherein the sensor is integrated with the electrode.

34. – 61. (Canceled)

62. (Withdrawn) A method of ablating electrically conductive pathways in heart tissue within the body cavity of a patient, comprising:

positioning a conductive element within the body cavity adjacent the selected heart tissue;

supplying power to the conductive element;

sensing with a sensor positioned adjacent the conductive element the vibration of the heart tissue; and

reducing power to the conductive element when the vibration reaches a given value.

63. (Withdrawn) The method of claim 62, further comprising:

halting the power when the vibration reaches a given value.

64. (Withdrawn) The method of claim 62, further comprising:

supplying fluid from a fluid supply to the heart tissue; and

halting the fluid supply when the vibration reaches a given value.

65. (Withdrawn) The method of claim 62 further comprising:

sending a signal from the sensor to a switch to reduce the power.

66. (Withdrawn) The method of claim 62, further comprising:

providing output from an output device when the vibration reaches a given value.

67. (Withdrawn) The method of claim 66 further comprising:
sending a signal from the sensor to the output device; and sending an indicator signal from the output device.

68. (Withdrawn) The method of claim 62 wherein the sensor is a piezoelectric crystal.

69. (Withdrawn) The method of claim 62 wherein the sensor is a piezoelectric polymer.

70. (Withdrawn) The method of claim 62 wherein the sensor is integrated with the conductive element.

71. (Withdrawn) A method of ablating organic tissue, comprising:
positioning a conductive element adjacent the organic tissue;
supplying an ionic fluid between the conductive element and the organic tissue;
supplying electrical power to the conductive element and the ionic fluid;
sensing with a sensor positioned adjacent the conductive element
the vibration of the organic tissue; and
reducing power to the conductive element when the vibration reaches a given value.

72. (Withdrawn) The method of claim 71, further comprising:
halting the electrical power when the vibration reaches a given value.

73. (Withdrawn) The method of claim 71, further comprising:
halting the ionic fluid supply when the vibration reaches a given value.

74. (Withdrawn) The method of claim 71 further comprising:
sending a signal from the sensor to a switch to reduce the electrical power.

75. (Withdrawn) The method of claim 71, further comprising:

providing output from an output device when the vibration reaches a given value.

76. (Withdrawn) The method of claim 75 further comprising:

sending a signal from the sensor to the output device; and sending an indicator signal from the output device.

77. (Withdrawn) The method of claim 71 wherein the sensor is a piezoelectric crystal.

78. (Withdrawn) The method of claim 71 wherein the sensor is a piezoelectric polymer.

79. (Withdrawn) The method of claim 71 wherein the sensor is integrated with the conductive element.

EVIDENCE APPENDIX

All the evidence related to this Appeal is on the record and before the Board. therefore, no additional evidence is identified in this Appendix.

RELATED PROCEEDINGS APPENDIX

There are no additional related proceedings to be considered in this Appeal. Therefore, no such proceedings are identified in this Appendix.